Proposed Rules for Adoption by the State Board of Health include:

"The department shall implement screening tests for biotinidase deficiency, galactosemia, homocystinuria, maple syrup urine disease and medium chain acyl-coA dehydrogenase deficiency beginning in January 2004 Screening for these disorders shall be fully implemented as quickly as feasible and not later than June 2004."

The additional fee increase is expected to be $21.50 ($61.90 total for each screen) and may be phased in as disorders are added

Impacts Regarding Proposed Rules Chapter 246-650 WAC, Newborn Screening

- Social Impact since it directly affects all newborns, parents of newborns, hospitals and birthing centers, pediatric health providers, and the State Department of Health.
- Economic Impact because the cost in dollars of early identification and treatment of affected infants is less than the cost of maintaining untreated children in institutions and special care programs.
- Emotional Impact on the child and parents when they discover that Washington purchased the equipment, trained and hired personnel, and took steps to perform only a small sub-set of treatable disorders which can be detected with the instrumentation.
- Financial impact on state (over 40% of births are paid for by Medicaid) and hospital/insurance/patients.

Problems with Proposed Implementation

- Statutory provisions in Chapter 70.83 RCW, are clear that it is the "policy of the state of Washington to make every effort to detect as early as feasible and to prevent where possible phenylketonuria and other preventable heritable disorders leading to developmental disabilities or physical defects."

  One of the technologies (Tandem Mass Spectrometry MS/MS) that will be required to be purchased in order for implementation of additional screening is capable of screening for many disorders at the same time with a low false-positive rate (WHHannon, SDGrosse, BLTherrell et al. Using Tandem Mass Spectrometry for Metabolic Disease Screening Among Newborns. MMWR April 13, 2000.) Washington is proposing to utilize the equipment in an inefficient way by not analyzing the other 20 metabolites possible through use of MS/MS (See article above).

- Costs per quality-adjusted life year saved by MS/MS screening for inborn errors of metabolism compare favorably with other mass screening programs, including those for breast and prostate cancer (Pediatrics 2002; 110:781-786).
- Development of expertise in MS/MS is an involved process as the technology is not “turn-key”. Washington does not have the expertise in house to run or interpret results.
- The Board should consider public fiscal policy associated with lack of full utilization of expensive equipment.
- Washington already has the most expensive cost per test in the United States. The proposed rule does nothing to rectify this problem and uses the same people to institute the additional tests who created the previous situation.

Solutions for Strengthening Proposed Rules

- Amend language to include or license private providers of newborn screening with experience in the field.
- Require broader participation by the private sector through establishing formal membership on Newborn Screening Advisory Committee. Existing make-up of committee is ad hoc and heavily influenced by the State Public Health Laboratory who may wrongly perceive private laboratories with greater capabilities as a threat.
- Ensure that appropriate increase in fees goes to support follow-up program and the specialists associated with care of affected newborns.
- Amend language to include consequences for failing to meet deadlines for full implementation of additional disorders.
- Require that the Board reconvene not later than July 1, 2004 to assess whether screening for this small sub-set of disorders is fully implemented as required by WAC 246-650-030.
- Require that proposed rules are implemented in compliance with RCW Chapter 70.83.
- Consider impact within healthcare delivery system of utilizing private laboratories that have expertise to perform screening using one sample rather than two samples as is currently performed.